Message

From: Ortiz, Nina [Ortiz.Nina@epa.gov]
Sent: 2/16/2022 8:18:43 PM
To: Pierce, Amanda [pierce.amanda@epa.gov]; Striegel, Wiebke [Striegel.Wiebke@epa.gov]; Kirk, Cassandra [kirk.cassandra@epa.gov]; Welch, Kara [welch.kara@epa.gov]; Piombino, Michael [Piombino.Michael@epa.gov]
CC: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Subject: RE: Draft language for adult traps near tet sources

Thanks Amanda!

For the group:
I'll be sending around an invite so we can discuss the most recent changes to the trapping and storm language prior to meeting with Oxitec tomorrow. If you can, take a look at the document Matt just sent.

Thanks!
Nina

From: Pierce, Amanda <pierce.amanda@epa.gov>
Sent: Wednesday, February 16, 2022 2:51 PM
To: Ortiz, Nina <Ortiz.Nina@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Welch, Kara <welch.kara@epa.gov>; Piombino, Michael <Piombino.Michael@epa.gov>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Hi Nina,

Below is the suggested term based on our meeting:

Ex. 5 Deliberative Process (DP)

Amanda

From: Ortiz, Nina <Ortiz.Nina@epa.gov>
Sent: Wednesday, February 16, 2022 11:32 AM
To: Pierce, Amanda <pierce.amanda@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Sure thing! Below is the most recent version of this term:

Three adult mosquito traps must be placed within 100 m from the outer edge of potential environmental tetracycline sources (as identified in term #1) that are located within 1,000 m of any OX5034 release point. When placement of all three traps is not feasible, a justification for the use of fewer traps must be provided. For female Ae. aegypti captured in these traps, Oxitec must determine the presence of the genetic cassette (vector pOX5034) following the standard operating procedures QD-R-00109 or QD-R-00108 (qPCR or endpoint PCR, respectively) once per month.

From: Pierce, Amanda <pierce.amanda@epa.gov>
Sent: Wednesday, February 16, 2022 11:10 AM
To: Ortiz, Nina <Ortiz.Nina@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Thanks, Nina. Kara and I are meeting with Mick later today to discuss these points and we'll get back to you. Will you send the latest language for us to look at too?

Thanks!
Amanda

From: Ortiz, Nina <Ortiz.Nina@epa.gov>
Sent: Tuesday, February 15, 2022 4:57 PM
To: Pierce, Amanda <pierce.amanda@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Hey everyone,

After this morning's meeting with Oxitec where they asked for clarification on the testing scheme, I wanted to get your feedback on a few considerations to have something ready to present during Thursday's meeting.

A quick refresher on our conversation- Oxitec collects samples from traps 1x/week into a catch bag, collecting a total of 4 catch bags per month. Although there are some hesitancies on their end to test all 4 catch bags, I would prefer that they do since the goal of asking them to place these traps is to monitor for female OX5034 adults. That being said, here are some questions I have about the logistics of testing all adult females captured in these traps:

- Do we know roughly how many females are expected to be captured in each trap?
- Would it be feasible to test all catch bags every month?
- As a hypothetical, let's say they capture ~100 females in one week. Since the goal of this term is only to test for presence of the OX5034 genetic cassette, would we be comfortable asking them to pool samples? (For example, running 10 samples in a well)

Thoughts on this?
-Nina

From: Pierce, Amanda <pierce.amanda@epa.gov>
Sent: Monday, February 14, 2022 1:53 PM
To: Ortiz, Nina <Ortiz.Nina@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Looks great. Thanks Nina!

From: Ortiz, Nina <Ortiz.Nina@epa.gov>
Sent: Monday, February 14, 2022 1:32 PM
To: Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Of course! That works for me.

Does anyone have any other edits they'd like to make?

From: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Sent: Monday, February 14, 2022 12:30 PM
To: Ortiz, Nina <Ortiz.Nina@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Hello Nina,

Could we simplify this to say: "*For female Ae. aegypti captured in these traps, Oxitec must determine the presence of the genetic cassette (vector pOX5034) following the standard operating procedures QD-R-00109 or QD-R-00108 (qPCR or endpoint PCR, respectively)* ~~*x amount of times per month/week*~~ *once per month.*" ?

This is the interval we had in the term dealing with the non-fluorescent larvae.

From: Ortiz, Nina <Ortiz.Nina@epa.gov>
Sent: Monday, February 14, 2022 12:01 PM
To: Pierce, Amanda <pierce.amanda@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

SO helpful! Thanks Amanda!

Here is some draft language for term #2:

Three adult mosquito traps must be placed within 100 m from the outer edge of potential environmental tetracycline sources (as identified in term #1) that are located within 1,000 m of any OX5034 release point. When placement of all three traps is not feasible, a justification for the use of fewer traps must be provided. For female Ae. aegypti captured in these traps, Oxitec must determine the presence of the genetic cassette (vector pOX5034) following the standard operating procedures QD-R-00109 or QD-R-00108 (qPCR or endpoint PCR, respectively) x amount of times per month/week.

I think up for discussion is the frequency of testing.

From: Pierce, Amanda <pierce.amanda@epa.gov>
Sent: Monday, February 14, 2022 11:40 AM
To: Ortiz, Nina <Ortiz.Nina@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Attached is the issuance letter and below is the term:

Oxitec must conduct continuous weekly monitoring for fluorescent larvae at release sites as indicated in the section G experimental program (sections 5.2.6.1 and 5.9.4.1). From the reared field-collected individuals, Oxitec must determine the presence of the genetic cassette (vector pOX5034) in a minimum of 150 non-fluorescent adult female *Ae. aegypti* following the standard operating procedures QD-R-00109 or QD-R-00108 once per month. If at any time during the course of the EUP Oxitec finds female individuals containing the OX5034 genetic construct surviving to adulthood Oxitec must take the following remediation actions: immediately cease releases of all OX5034 mosquitoes, as soon as practicable apply adulticide and larvicide pesticides to the treated area where the surviving females were detected and continue to monitor for the presence of the OX5034 genetic construct in female *Ae. aegypti* until OX5034 mosquitoes are no longer found for at least two successive mosquito generations, a minimum of 10 weeks. EPA may require additional applications of adulticides and larvicides if fluorescent mosquitoes continue to be found in the treated area after the initial detection.

From: Ortiz, Nina <Ortiz.Nina@epa.gov>
Sent: Monday, February 14, 2022 11:24 AM
To: Kirk, Cassandra <kirk.cassandra@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Thanks everyone!

Cassie, thank you for the reminder and link! I'm looking up the labels for those products today.

I agree with the group on removing the bit about trap arrangement. Additionally, below is the language I've found for PCR testing taken from section 4.6.5.1 in Kara's section G:

The fluorescent marker is readily visible in all life-stages apart from eggs and will be used for OX5034 identification (GL-SOP-00052). Molecular analyses by PCR will be used to validate marker identifications in a minimum number of 40 fluorescent and 40 non-fluorescent screened individuals (QD-R-00109 or QD-R-00108). It is expected that this will be required only once, to ensure accurate identification by trial staff. In addition, all individuals will be taxonomically identified to genus and/or species level. Fluorescence screening will also be used to assess penetrance of the female-specific self-limiting gene (see Section 4.6.5.2 for ovitrap monitoring details and GL-SOP-00052 for larval rearing methods as part of penetrance testing). In addition, the requirement to test 150 non-fluorescent females reared from ovitraps (as described in the EUP issuance letter dated 30 Apr 2020) is carried out once per month, and will continue throughout the transgene persistence measurements after the cessation of releases, noting that the total number of non-fluorescent females available for screening after the end of releases may fall below 150 per month as this is likely to coincide with the low mosquito season in both trial locations. In this case, Oxitec would test as many non-fluorescent females as were available, up to 150 in total per month.
Please note that field-collected samples of Aedes aegypti may be taken and stored for subsequent analyses of genetic diversity and introgression of background genes.

If this is the portion Amanda was referring to, I've highlighted the language that we could include in our terms, minus the requirement of the 40 screened individuals.
Thoughts on this?

From: Kirk, Cassandra <kirk.cassandra@epa.gov>
Sent: Friday, February 11, 2022 12:26 PM
To: Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Welch, Kara <welch.kara@epa.gov>; Ortiz, Nina <Ortiz.Nina@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

I am on board with these comments!

From: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Sent: Friday, February 11, 2022 12:03 PM
To: Pierce, Amanda <pierce.amanda@epa.gov>; Welch, Kara <welch.kara@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Ortiz, Nina <Ortiz.Nina@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

I think you bring up some good points there on the request for how they place the traps. I don't personally have any set criteria on how they would arrange the traps at those sites, so requesting this information wouldn't really be useful. So I agree with removing the sentence.

On the PCR issue, I forgot that we specifically mentioned PCR in the other term, so I agree with your suggestion. It definitely doesn't hurt to be more specific!

Wiebke

From: Pierce, Amanda <pierce.amanda@epa.gov>
Sent: Friday, February 11, 2022 9:00 AM
To: Welch, Kara <welch.kara@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Ortiz, Nina <Ortiz.Nina@epa.gov>
Cc: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Oh also one additional thought, I think we should specify that we want them to do PCR using the same language as in the fluorescent larvae term. The fluorescent larvae term also includes time frames for monitoring (i.e., weekly monitoring and monthly PCR). Consider whether this should be included here too.

From: Pierce, Amanda
Sent: Friday, February 11, 2022 8:53 AM
To: Welch, Kara <welch.kara@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Ortiz, Nina <Ortiz.Nina@epa.gov>
Cc: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

My suggestion for #2 would be to delete a single sentence:

> Three adult mosquito traps must be placed within 100 m from the outer edge of potential environmental tetracycline sources (as identified in term #1) that are located within 1,000 m of any OX5034 release point. Female mosquitoes captured in these traps must be analyzed for the presence of the OX5034 genetic cassette. ~~Before start of the OX5034 releases, provide a trap placement layout indicating the distances between the traps.~~ When placement of all three traps is not feasible, a justification for the use of fewer traps must be provided.

This sentence would require them to send us something (presumably for review?) for every tet source prior to release. Do we know the criteria which we would judge whether the distance between traps is considered sufficient? If we have that criteria, I think it would be better to just include it in the term given that we provide them flexibility on trap number anyway in the following sentence. If we don't have criteria, then just removing it seems fine to me.

Amanda

From: Welch, Kara <welch.kara@epa.gov>
Sent: Thursday, February 10, 2022 5:30 PM
To: Kirk, Cassandra <kirk.cassandra@epa.gov>; Ortiz, Nina <Ortiz.Nina@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>
Cc: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Thanks Cassie and Nina.

Nina, please let me know if the language changes per Cassie's comment below. Besides that, I believe the language looks good to me.

I appreciate the team working through these tough issues.

My best,
Kara

From: Kirk, Cassandra <kirk.cassandra@epa.gov>
Sent: Thursday, February 10, 2022 5:11 PM
To: Ortiz, Nina <Ortiz.Nina@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Cc: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Subject: RE: Draft language for adult traps near tet sources

Thanks for this Nina! Did you check the product labels to see if application is limited to apples and pears? I thought when I was running through the labels to see which products were used on palm trees that I saw some additional fruits. Here is the link to the label database in case you don't have it: https://www.epa.gov/ingredients-used-pesticide-products/how-search-information-about-pesticide-ingredients-and-labels#PPLS

Also, I think yesterday we decided that simply stating "commercial livestock" was adequate despite FDAC's concern since they talking about backyard and feral chickens in the Keys which are not commercial livestock.

Cassie

From: Ortiz, Nina <Ortiz.Nina@epa.gov>
Sent: Thursday, February 10, 2022 4:19 PM
To: Kirk, Cassandra <kirk.cassandra@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Cc: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Subject: Draft language for adult traps near tet sources

Hi all,

Attached is the draft language for placing traps within 1000 m of tetracycline sources. Can you review and make suggestions at your earliest convenience?

Kara, term #2 (trap placement) is relevant to the Section G review. Will you double check that this is in line with the Section G?

Thanks everyone!
Nina